Message

From: Rosen, Bailey [Rosen.Bailey@epa.gov]
Sent: 9/2/2020 9:14:19 PM
To: OPP FEAD CSB [OPP_FEAD_CSB@epa.gov]; Bolen, Derrick [bolen.derrick@epa.gov]; Cyran, Carissa [Cyran.Carissa@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Fischer, David [Fischer.David@epa.gov]; Giddings, Daniel [giddings.daniel@epa.gov]; Grable, Melissa [Grable.Melissa@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Kaiser, Sven-Erik [Kaiser.Sven-Erik@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Labbe, Ken [Labbe.Ken@epa.gov]; Lieberman, Paige [Lieberman.Paige@epa.gov]; Mills, Madeline [Mills.Madeline@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Sullivan, Melissa [sullivan.melissa@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]
Subject: OCSPP News for September 2, 2020

OCSPP News Round-Up

TSCA

- Chemical Watch 9/1; Big interview: Alexandra Dunn – EPA gears up for risk management of chemicals under TSCA
- The Toy Book 9/1; THE TOY ASSOCIATION MEETS WITH EPA TO ADVOCATE FOR RISK MANAGEMENT RULE
- Bloomberg Law 9/1; Wisconsin Law on PFAS Takes Effect, but With Details Unclear
- Bloomberg Law 9/1; 3M Investor Lawsuit Over 'Forever Chemicals' Stays in New Jersey
- Inside TSCA 9/1; EPA Renews Bid To End Novel Suit Seeking TSCA Asbestos Reporting Rule
- Inside TSCA 9/1; California Faulted Over Plan To Narrow Policy On PFAS In Food Packaging
- Inside TSCA 9/2; EPA's Paintstripper Ban Hints At Challenges With TSCA Section 6 Rules

Pesticides

- AG Daily 9/2; EPA supports technology to improve sustainability & benefit farmers
- Bloomberg Law 9/1; EPA's Pesticide Approval Risks Colony Collapse, Beekeepers Say

Blogs/OpEd/Other

- JD Supra Blog 9/1; EPA Chemical Risk Evaluations – Stakeholders Diverge on Whether and How EPA Must Include Dietary Exposures
- Asbestos.com 9/2; Peer Review Finds EPA's Asbestos Risk Evaluation Flawed

++

Big interview: Alexandra Dunn – EPA gears up for risk management of chemicals under TSCA
Chemical Watch
https://chemicalwatch.com/147983/big-interview-alexandra-dunn-epa-gears-up-for-risk-management-of-chemicals-under-tsca

The head of the agency's chemicals and pesticides office tells Terry Hyland how it is approaching risk management rulemaking under TSCA, what changes might be in store for TSCA fees, and how the EPA has responded to Covid-19

Four years on from the overhaul of TSCA, the spotlight is now on the development of risk management rules. The two-year clock to finalise rules has already started for methylene chloride and 1-bromopropane, the first two risk evaluations completed under the amended law, and eight more are on the way. Meanwhile, final rules on five persistent, bioaccumulative and toxic chemicals (PBT) are due by the end of this year.

For Alexandra Dunn, the EPA's Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP), ensuring the risk management process works means getting to know the users of the chemicals under review.

"We want to know what ideas our colleagues have around risk management approaches, how effective they can be, what impact they might have on businesses, and we have to do this under an aggressive timeline," Ms Dunn says during a phone interview. "We are going to develop a transparent proactive and meaningful programme around risk management."

Developing regulations to manage any unreasonable risks from chemicals is only a slice of the issues Ms Dunn's office has handled in the 20 months since she took over the agency's chemical and pesticides office. The EPA is also poised to release final scope documents outlining the breadth of review for the next 20 substances to be evaluated under TSCA, and later this year it will propose revisions to its TSCA fees rule.

Risk management ramps up

The agency is at the early stages of the risk management process for a number of chemicals. It has so far finalised risk evaluations for methylene chloride and 1-bromopropane (1-BP). For both, the EPA found unreasonable risks associated with a number of their applications.

Those findings started a new clock, this time on the risk management process. The EPA now has one year from the date each evaluation was finalised to make proposals to manage identified risks, and an additional year to finalise the risk management rules.

That process will involve extensive outreach, as well as efforts to educate the public and any entities subject to regulatory action on managing chemical risks, Ms Dunn says.

The OCSPP plans to "go above and beyond" the usual stakeholder consultations to talk, she says, not just with chemical manufacturers, but also with downstream users, environmental groups and other affected communities. The goal, she says, is "to make sure we fully understand how chemicals are currently used, but also what the risk management decisions will mean".

Ms Dunn says the agency also plans to launch a series of webinars to provide more information about the risk management process and the "tools" the agency can use to manage risks from chemicals, including work practices, engineering controls, administrative controls that could limit employee exposure, and others.

Improvements are also planned for the section of the agency's website dealing with chemicals. Ms Dunn says the EPA plans to provide "clear and consistent" contacts for each chemical substance, and to make it easier for anyone to keep track of the assessment and management of existing chemicals and engage with the agency.

She adds that her office has learned a great deal through its work on rules for the five PBTs. The agency last year proposed partial bans on four of the five substances, which were subject to fast-tracked action under the 2016 revisions to TSCA.

"If you look at those rules, you'll see we spent a lot of time getting to know the users of those chemicals," Ms Dunn says.

"One thing we've seen is a desire to retain" some commercial applications for substances, but they may not be as safe for use by consumers who usually do not use the same protective equipment that might be used in the workplace, she says. That was the case in early 2019 when the agency banned methylene chloride in consumer paint removers, but not in commercial uses.

The EPA chemicals head says the agency is reviewing a request from industry groups to develop a rule to guide the risk management process. But, she says, "the timing of that request poses some challenges". Rulemaking takes several years and the agency is already involved in the risk management process for some substances.

No decision has yet been made on the request, Ms Dunn says.

TSCA fees

The EPA also has begun work to revise its 2018 TSCA fees rule, with a proposal expected in December before a final rule in October 2021.

The agency now has more data to work with as it prepares to revise the fees rule, Ms Dunn explains. The EPA has been tracking costs associated with the first ten chemical reviews, and has data going back to 2017.

"We've learned quite a few things," she says.

Proposed changes to the rule are expected to include the exemptions outlined in March. Those allowed companies that import articles containing high-priority chemicals, or those who manufacture them only as impurities or byproducts, to avoid having to identify themselves for TSCA fee payments.

It is too soon to say what else will be included in the proposed changes to the fees rule, Ms Dunn says. However, she adds the agency would look at the exemptions as well as other potential changes "so we can focus fees on those who are true manufacturers of the chemicals".

"That's where we believe Congress intended us to go," she says. "We cast a bit of a broad net [in 2018] and learned a lot."

Responding to Covid-19

Roughly a third of Ms Dunn's time in post at the OCSPP has coincided with the global Covid-19 pandemic that has forced the agency's 14,000 staff into remote working.

Despite the challenges posed by the coronavirus, Ms Dunn says the agency's staff "has not missed a beat". She highlighted the EPA's work on the pandemic, including expediting the clearance process for more than 400 disinfectant products that are now listed as effective against Covid-19.

She says that the EPA Administrator, Andrew Wheeler, has asked agency offices to see which of the changes made during the outbreak should be made permanent.

Generally, doing this "would require formal rulemaking", she says, "and we would be prepared to do that if the effort would allow us to put in place something that is very effective".

"We are just very pleased with the fact that we've kept moving with the aggressive timeline on TSCA," she adds.

Priorities for end of 2020

Heading into the autumn, Ms Dunn says her top TSCA-related priorities for the remainder of the year are to complete the final rules for the PBTs, issue final scope documents for the next 20 chemical risk evaluations, publish a finalised proposal on dust lead clearance levels, and completing the first ten chemical reviews.

"We knew that going into this June, that it was going to be difficult" to meet all the statutory deadlines associated with the fourth anniversary of TSCA, Ms Dunn says, "but we plan to finish this work by the end of the calendar year".

THE TOY ASSOCIATION MEETS WITH EPA TO ADVOCATE FOR RISK MANAGEMENT RULE

James Zahn, The Toybook

https://toybook.com/the-toy-association-meets-with-epa-to-advocate-for-risk-management-rule/

The Toy Association continues to advocate for its members on a variety of fronts, including those at the crossroads of technical and environmental concerns.

On Aug. 28, The Toy Association's Alan Kaufman, senior vice president of technical affairs, met with U.S. Environmental Protection Agency (EPA) Administrator Andrew Wheeler and Alexandra Dunn, assistant administrator at the U.S. EPA Office of Chemical Safety and Pollution Prevention, to discuss a requested risk management rule that is viewed as a necessary action to implement the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

The Toy AssociationThe Lautenberg Act was signed into law in 2016 to amend and update the Toxic Substances Control Act (TSCA) of 1976 that regulates the use of new and existing chemicals used in manufacturing.

Earlier this year, The Toy Association joined The American Coatings Association, The National Association of Home Builders, The National Association of Manufacturers, and The U.S. Chamber of Commerce in crafting a petition asking the EPA to enact a rule that "would ensure procedural consistency, guidance, and transparency for the agency's risk management process, giving members greater predictability about how identified risks would be regulated for specific uses."

According to The Toy Association, Wheeler indicated agreement that such a rule may be necessary pending a more detailed briefing in the future.

Since the EPA is not likely to move on the issue before January, The Toy Association is prepared to reinforce its requests in the event that there is a change in administrations following the November elections.

Toy Association members can learn more about the issue here.

Wisconsin Law on PFAS Takes Effect, but With Details Unclear

Stephen Joyce, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/wisconsin-law-on-pfas-takes-effect-but-with-details-unclear?usertype=External&bwid=00000174-4525-d595-a9fc-edb503de0001&qid=6969933&cti=FGOV&uc=132000080&et=CURATED_HIGHLIGHTS&emc=neve_hlt%3A18&context=email&email=00000174-4ad7-d58b-a7f4-eff747e90000&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzQtNDUyNS1kNTk1LWE5ZmMtZWRiNTAzZGUwMDAxIiwic2lnIjoiYXZ0VS90NHFGaGNMaUVrNm9BRStHNCtEZmxVPSIsInRpbWUiOiIxNTk4OTkwNDU5IiwidXVpZCI6InhWdUtJZUR0bFBvaXRtK1JnNVYwMmc9PXc1a24vQm9saWxleHFqQnpoeTUwNFE9PSIsInYiOiIxIn0%3D

- Agency postpones vote on disputed rule until September
- Industry and regulators still differ on rule's scale, scope

A Wisconsin law entered into force on Tuesday, aiming to curb releases of so-called forever chemicals in the environment—but without any rules to guide its interpretation, implementation, or enforcement.

Wisconsin businesses initially supported the legislation, 2019 Wisconsin Act 101. It passed in February and aims to mitigate the harmful effects of discharging firefighting foams containing poly- and perfluoroalkyl substances known as PFAS.

But businesses balked when the Wisconsin Natural Resources Board tried to agree on an emergency rule implementing the legislation in August.

"The goal needs to be, we have to achieve the level of environmental and public health protection and we need to do it in the most cost-effective way. And I think there's a way to get there," said Scott Manley, executive vice president of government relations at Wisconsin Manufacturers & Commerce.

The rulemaking is one of Wisconsin's latest efforts to reduce environmental risks associated with PFAS, a group of substances known as forever chemicals because of their ability to persist in the environment and in human bodies.

The law bans the use or discharge of Class B firefighting foam, which is designed for use on flammable liquid fires, with two exceptions: its use in emergency firefighting operations or for testing in an appropriately equipped facility. Such foam, often used on military bases or at airports, is one of the most widespread causes of PFAS contamination in waters nationwide.

Two-Rule Process

Wisconsin regulators have detected PFAS in the state's air, sediment, and surface and ground waters, as well as the soil at state industrial sites. Epidemiologist have linked exposure to PFAS to several diseases and types of cancer.

State Department of Natural Resources Secretary Preston Cole in June approved a statement of scope for an emergency rule to be completed by Tuesday, to provide timely compliance guidance as the law came into effect. That rule was meant to be superseded by a second, more comprehensive rule to be concluded at a later date.

But Manley's group, the Wisconsin Paper Council, the Wisconsin Water Alliance, and others groups representing Wisconsin companies affected by the legislation objected to the rule's scope, arguing it went beyond the statement of scope and therefore violated state law. And wastewater treatment facility operators and others objected to the effluent limits in the rule, saying they were too restrictive.

Several environmental groups, however, support the rule as written. Clean Wisconsin, River Alliance of Wisconsin, Midwest Environmental Advocates, Sierra Club-Wisconsin, and others said they were "extremely disappointed" the board didn't approve the rule at its August meeting, claiming profitable Wisconsin industries effectively blocked the rule's "modest protections" against PFAS.

The resulting impasse has left companies and regulators without clear guidance on how the law will be enforced, or how companies should interpret specific terms contained in the proposed rule, Manley said.

The natural resources board is expected to vote on a revised proposed rule at its Sept. 22-23 meeting.

A state Department of Natural Resources spokeswoman didn't respond to a request for comment.

The Sierra Club has received funding from Bloomberg Philanthropies, the charitable organization founded by Michael Bloomberg. Bloomberg Law is operated by entities controlled by Michael Bloomberg.

3M Investor Lawsuit Over 'Forever Chemicals' Stays in New Jersey

Jennifer Bennet, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/3m-investor-lawsuit-over-forever-chemicals-stays-in-new-jersey?usertype=External&bwid=00000174-4a34-dd3f-ad77-fab768d30001&qid=6969933&cti=FGOV&uc=1320000080&et=CURATED_HIGHLIGHTS&emc=neve_hlt%3A19&context=email&email=00000174-4ad7-d58b-a7f4-eff747e90000&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzQtNGEzNC1kZDNmLWFkNzctZmFiNzY4ZDMwMDAxIiwic2lnIjoicHlKdDNHd0NETnJuRWkzOXJSZUFKeTZpaXBnPSIsInRpbWUiOiIxNTk4OTkwNDU5IiwidXVpZCI6InhWdUtJZUR0bFBvaXRtK1JnNVYwMmc9PXc1a24vQm9saWxleHFqQnpoeTUwNFE9PSIsInYiOiIxIn0%3D

- Company didn't meet burden to transfer case
- N.J. has interest in resolution, federal judge says

3M Co. must face a would-be class suit, alleging it hid internal evidence of PFAS toxicity, in federal court in New Jersey after a judge rejected the company's bid to transfer the case to Minnesota.

The St. Paul-based manufacturing conglomerate asked the U.S. District Court for the District of New Jersey to transfer the action to a federal court in Minnesota. The case could have been filed there originally, but private- and public-interest factors "favor the case remaining in" the New Jersey court where the investors sued, Judge Claire C. Cecchi's ruled Monday in an unpublished opinion.

PFAS, or man-made per- and polyfluoroalkyl substances, are also known as "forever chemicals" for their capacity to accumulate in people and the environment and hang around for years. Studies have linked some of the chemicals to low infant birth weights, cancer, and thyroid hormone disruption.

The investors' forum preference and 3M's ability to make its witnesses available for trial in New Jersey weigh against transferring the case, Cecchi said. And "3M's size, resources, and ongoing litigation in this district in other matters indicate that it is not overly burdensome for the company to conduct litigation here."

New Jersey was allegedly "greatly affected by 3M's PFAS" and the proposed class will likely include New Jersey residents, so it makes sense for courts in the state to rule on the controversy, the opinion said. And federal judges in New Jersey "regularly handle claims under the Exchange Act and are quite familiar with such matters," Cecchi said.

3M didn't meet its "burden of showing that it is inefficient, unmanageable, or unduly burdensome to proceed with this matter in" New Jersey, so the case won't be transferred to Minnesota, the opinion said.

Robbins Geller Rudman & Dowd LLP and Motley Rice LLC served as lead counsel to the investors. Calcagni & Kanefsky LLP and Freshfields Bruckhaus Deringer US LLP represented 3M.

The case is In re 3M Co. Sec. Litig., D.N.J., No. 19-cv-15982, unpublished 8/31/20.

EPA Renews Bid To End Novel Suit Seeking TSCA Asbestos Reporting Rule

Maria Hegstad, Inside TSCA

https://insideepa.com/tsca-news/epa-renews-bid-end-novel-suit-seeking-tsca-asbestos-reporting-rule

EPA is renewing its efforts to end potentially precedential TSCA suits from Democratic state attorneys general and environmentalists seeking to force the agency to require companies to report their uses of asbestos, filing a summary judgment motion that argues the plaintiffs lack standing and failed to meet the burden of proof.

"In their motions for summary judgment, Plaintiffs speculate that the reporting requirements for which they advocated in their administrative petitions would reveal new information regarding current uses of asbestos within the United States. But EPA cannot regulate on speculation," EPA says in a Sept. 1 brief in the consolidated cases Asbestos Disease Awareness Association (ADAO), et al. v. EPA and State of California, et al. v. EPA.

EPA argues that plaintiffs "fail to show that EPA overlooked potential uses or exposures when the agency denied the administrative petitions" asking EPA to write a Toxic Substances Control Act (TSCA) section 8 rule altering EPA's existing Chemical Data Reporting Rule (CDR) to require companies to report their uses of asbestos to the agency.

"And, just as Plaintiffs failed to meet their burden before the agency to show that it was 'necessary' to initiate rulemaking, [per TSCA section 21(b)(1)], Plaintiffs fail to meet their burden here to show that EPA's denial of their petitions was arbitrary or capricious."

The suit is the second since Congress reformed the law in 2016 that challenges an EPA denial of a petition, filed under TSCA section 21, asking the agency to take certain regulatory action.

In the first such case, Food & Water Watch, Inc., et al. v. EPA, Judge Edward Chen, who is overseeing both TSCA petition cases, last month delayed the novel lawsuit seeking to force EPA to regulate drinking water fluoridation under TSCA after a days-long trial.

Like the fluoride trial, the pending asbestos case is already setting precedents. Chen, last November, rejected EPA's motion to dismiss ADAO's suit, a potentially precedent-setting ruling allowing environmentalists to pursue their challenge under the Administrative Procedure Act (APA) rather than TSCA.

The states' TSCA petition that EPA rejected followed a nearly identical petition filed in 2018 from ADAO and other public health advocates and environmentalists. Each asked EPA to require companies to produce asbestos exposure and use information as part of future quadrennial CDR rules.

EPA denied both TSCA section 21 petitions and both groups challenged those denials.

EPA's latest filing in the asbestos suit responds in part to summary judgment motions the plaintiffs filed in July charging that EPA's petition denials violated the APA and the agency's failure to require such reporting means officials lack access to data they need to complete their pending evaluation of the mineral.

"EPA's unlawful and arbitrary denial of the Petition deprives EPA, as well as the States and the general public, of the data that the reporting requirements sought by the Petition would have provided, perpetuating a status quo where EPA makes regulatory assessments with unreliable and inadequate information," states a July 14 summary judgment motion from attorneys general in California, Connecticut, the District of Columbia, Hawaii, Maine, Maryland, Minnesota, New Jersey, Oregon and Washington.

Two Independent Reasons

But EPA reiterates many of its earlier arguments, telling Chen, who sits on the U.S. District Court for the Northern District of California, that he should rule for the agency "for two independent reasons": plaintiffs lack standing and "EPA's denial of the petitions was reasonable and well-supported."

On standing, EPA argues that ADAO and co-plaintiffs "did not proffer any evidence to establish that they have standing to bring this action" while the blue states argued they would be harmed by lack of information because EPA declined to require asbestos reporting.

But EPA cites the 1992 Supreme Court ruling Lujan v. Defs. of Wildlife to argue that "[e]ven if the States' evidence is accepted as true, their asserted injury is not 'likely, as opposed to merely speculative,' to be redressed by a favorable decision. The States thus fail to demonstrate that additional information reported to EPA by manufacturers, importers, or processors would be made available to the States or to explain specifically how additional asbestos reporting would support state programs."

For the merits, EPA argues that its denial of the plaintiffs' TSCA section 21 citizens' "petitions was reasonable and well-supported. Under [TSCA section 8(a)(1)(A)], Congress provided EPA with broad discretion to determine what reporting EPA 'may reasonably require.' EPA reasonably determined that removing certain reporting exemptions contained in the CDR Rule with respect to asbestos would not likely lead to the collection of new information. EPA's determination was based on extensive data collection and analysis."

The court has scheduled a hearing on the dueling motions for Nov. 12. -- Maria Hegstad (mhegstad@iwpnews.com)

California Faulted Over Plan To Narrow Policy On PFAS In Food Packaging

Curt Barry, Inside TSCA

https://insideepa.com/tsca-news/california-faulted-over-plan-narrow-policy-pfas-food-packaging

California toxics regulators are suggesting they will narrow the number of paper food-packaging products containing per- or polyfluoroalkyl substances (PFAS) potentially subject to an upcoming regulation, a move that is already drawing criticism from public health and environmental groups.

"This would be an unfortunate decision," says Andria Ventura, Clean Water Action's California toxics program manager. "Given the already slow pace of this program, and the serious consequences of continued use of PFAS in non-essential uses like packaging, not doing the entire scope of paper packaging would be a tremendous wasted opportunity."

Ventura is one of several advocates for public and environmental health who is expressing concern over the latest developments in the California Department of Toxic Substances Control's (DTSC) proposal to list paper, or "fiber-based," food packaging containing PFAS as a priority product under the state's Safer Consumer Products (SCP) green chemistry program.

Once a product is listed as a priority under the SCP program, companies are required to conduct chemical alternatives analyses to determine whether there are safer substitutes. Based on the results of the analyses, DTSC can eventually restrict or ban the original chemicals at issue in the products.

California is one of several states that is eying restrictions on food and other packaging containing PFAS. For example, New York's legislature in July approved legislation banning the sale or distribution of food packaging containing PFAS though Gov. Andrew Cuomo (D) has not yet indicated whether he will sign it.

And Washington state recently listed food and drink cans as well as leather and textile furnishings, that contain PFAS as priority products for regulation under its program to limit harmful releases.

DTSC staff held an Aug. 31 virtual public workshop to discuss their proposal -- focusing mainly on a product-chemical profile document dated July 2020 -- and receive input from stakeholders on a number of issues and questions.

DTSC is accepting written comments on the proposal until Sept. 13. Finalization of the rulemaking to list the items as priority products likely would not occur until well into 2021, officials indicate.

The product-chemical document notes that all PFASs are candidate chemicals under the SCP program "due to their designation on Dec. 22, 2015, as Priority Chemicals under the California Environmental Contaminant Biomonitoring Program."

Plant fiber-based food packaging products treated with PFASs for grease, oil, or water resistance "can expose humans and biota to PFASs during their manufacturing, use, and end-of-life," the document adds. "PFASs can migrate from food packaging into the packaged food, with migration rates dependent on the temperature, acidity, storage time, and fat content of the food. Used PFAS-treated paper, paperboard, and molded fiber food packaging products are sometimes composted, releasing PFASs into the compost. When used food packaging is sent to a landfill, the PFASs can migrate into landfill leachate, contaminating surface waters and the surrounding environment."

But André Algazi, chief of DTSC's chemical-product evaluation section, suggested during the Aug. 31 meeting the department may eventually narrow the number of products containing PFAS that would be subject to regulation under the current proposal.

"When we get to rulemaking, there's a good chance we will focus on one or more specific food packaging products. But we may not cover the breadth that's in the profile, but we may do more than one. So that will be determined in part by information we receive today and during this comment period."

'Focus Our Attention'

Following the meeting, a spokesman clarified Algazi's comment, saying DTSC is seeking advice on how to prioritize its focus. "We have made no decisions about which of these products we might tackle first. That was one of the reasons we asked the question at today's workshop. We're hoping stakeholders will suggest where we might first focus our attention," the spokesman said.

"It just means that the profile's definition of food packaging is very broad, and covers a range of molded fiber, coated paper, and paper board packaging products (for example, plates, clam shell boxes, French fry boats, bags, wraps, etc.). These products have different uses and different functional requirements with respect to each other. So it would make sense for us to address them as separate priority products," the spokesman added.

But environmentalists and public health groups argue in part that the DTSC rulemaking should include a broad swath of paper food packaging products because they claim there are adequate non-PFAS alternatives available now.

Elijah Butterfield, an environmental justice fellow at the Center for Environmental Health (CEH), recommended in written comments during the Aug. 31 meeting that DTSC prioritize "all molded fiber food packaging and food contact materials."

And Clean Water Action's Ventura, in written comments, urged DTSC not to prioritize types of PFAS food packaging "since the impacts are all of concern in terms of public health and the environment."

"We don't want a situation where we focus on one type of [packaging] and have businesses just move to another type that have PFAS," she said.

Butterfield added that an emerging concern is that COVID-19 "has caused many schools to unnecessarily replace their reusable foodware with single-use, molded fiber products. PFAS is especially harmful to children, and as an endocrine disrupting chemical, can adversely impact the immune system."

Factors To Consider

DTSC is asking stakeholders to provide comments and information related to a number of questions that were posed during the meeting, including several that appear to indicate DTSC's desire to narrow the focus of the rulemaking. These include: Which PFAS-containing food packaging products do you recommend DTSC prioritizes and why? Which specific plant fiber-based food packaging products: tend to contain PFASs most commonly? or tend to contain PFASs in highest concentrations?

In addition, DTSC staff asked: Which specific plant fiber-based food packaging products containing PFASs: are sold in highest volume? and tend to be composted?

"It's my impression that they will need to, or they feel they have to, narrow the rulemaking," says a source with a public health organization. "It's a guess as to whether they will have to significantly narrow it, but I think it's highly possible."

DTSC's decision on how to narrow the rulemaking is likely to depend in part on the information staff gathers about product markets, the source says. "If I was in their shoes and got data that said a particular category -- whether molded fiber cups or whatever -- if that was a sizeable proportion of the market, that would tell me a lot of people are eating or

drinking out of it and therefore exposure is likely to be high. . . . And therefore, there would be one datapoint to say, 'oh maybe we should prioritize this.'"

The source adds that DTSC officials highlighted that they have two leading criteria for identifying priority products -- adverse impacts and potential for exposure. "That seems to suggest that if they get one or two or three types of food packaging types that are really big on the market -- are being used a lot or being sold a lot and going to composting a lot -- I imagine that would play a pretty big role."

Other factors likely to be considered by DTSC include to what extent certain products have safer substitution chemicals available, the source adds. -- Curt Barry (cbarry@iwpnews.com)

EPA's Paintstripper Ban Hints At Challenges With TSCA Section 6 Rules
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/epa-s-paintstripper-ban-hints-challenges-tsca-section-6-rules

EPA's rule barring consumer use of paintstripping products containing methylene chloride -- the only TSCA risk management rule the agency has finalized -- portends future challenges EPA will face as it seeks to develop other rules under section 6 of the statute, particularly with regard to performing cost-benefit analyses, a TSCA attorney says.

James Votaw, a partner with the law firm Keller and Heckman, said during an Aug. 12 webinar that given the difficulty the agency faced quantifying costs and benefits from the single use regulated by the paintstripper ban, the agency may struggle to quantify costs and benefits of any future regulatory actions because the agency will likely have to address unreasonable risks from dozens of uses.

"Because [the methylene chloride rule] is so narrowly focused on single use -- by contrast EPA is looking at 40 or 50 individual uses for some of the other chemicals in the first 10 chemicals -- this is really a one off," he says.

James Votaw
James Votaw

Still, the rule remains the only finalized Toxic Substances Control Act (TSCA) section 6 rule that has been completed since Congress reformed the statute in 2016, and as such, he suggested that it bears reviewing for what it may suggest for future section 6 rules.

Under the revised law, EPA is generally required to determine whether substances' conditions of use pose "unreasonable risks" and then write rules to regulate such risks, taking into account the costs and benefits of its actions.

So far, the agency has finalized two of its first 10 evaluations -- for a host of uses of methylene chloride and 1-bromopropane -- each of which will require the agency to write risk management rules within three years.

But as the agency begins weighing any risk management actions, industry officials are already bracing for potential restrictions. For example, Votaw urged companies to look at EPA's upcoming risk management rules to determine whether they may impact companies' supply chains, adding that it is very hard for a company to respond to such a situation late in the game.

It is "important to start thinking early about data to generate to get you to the outcome you want," he said, adding that while there is no mandate in TSCA for a company to generate such data, the alternative is that EPA "will use what they have. Looking at benefits and costs for your technology may [mean it will] be identified as a beneficial alternate."

In addition, a coalition of downstream chemical users has petitioned EPA to revise existing risk management procedures that would provide some certainty on how to win compliance exemptions, waivers from certain restrictions, and other

flexibilities. Votaw noted that the methylene chloride rule "doesn't trigger a number of issues raised in the petition," such as replacement parts or critical use exemptions.

While few expect EPA to grant the petition, agency officials have sought to reassure industry that any risk management rules will be narrowly tailored.

Data Challenges

Still, Votaw says the agency will struggle to find data to develop cost-benefit analyses. While the paintstripper ban may be of "limited use" because its focus is so narrow, he says it nevertheless shows the "challenges EPA is going to have [when] looking at dozens and dozens of individual uses in these upcoming rules."

In the methylene chloride rule on paintstrippers, which EPA released last spring, the agency determined after its cost-benefit analysis to restrict consumers' access to paintstrippers containing the product by barring its sale in containers any smaller than 55 gallons. At the time, the agency also indicated that it may take action on occupational uses of such products in the future, but to date, has yet to do so.

The rule already faces multiple court challenges consolidated in a case before the U.S. Court of Appeals for the 2nd Circuit. Environmentalists and labor groups charge the rule is insufficiently protective, in large part because it does not address the risks that workers exposed to the chemical face, while a group representing makers and users of the products also challenged the rule, charging it would impose adverse unintended consequences by curbing some commercial uses.

Even as the rule faces legal challenges, Votaw says it also shows that one of the largest challenges for EPA and companies subject to any restriction in the future is going to be the data available for EPA to conduct cost-benefit analyses.

He says that while EPA conducted a cost-benefit analysis for the painstripper ban, the fact that the rule only focused on death from acute exposures helped simplify the agency's analysis.

"I think it's important to see that even with that very narrow scope for this rule . . . the agency really still struggled to provide any sort of really solid quantification of either the benefits or the costs," he says.

Votaw called EPA's cost estimate range of $3.8 million to $13.8 million "very soft." As a result, he says, "for future rules . . . there's a real data challenge and analysis challenge for pulling together this kind of information and doing the comparison and so the procedures the agency will use in the future are going to be important."

He noted that EPA's analysis included examining substitute products and whether they were beneficial and economically feasible.

"When it came to actually that process . . . lifecycle analysis and examining whether a substitution overall is beneficial or not, the agency in this case made the decision based simply on the toxicity level," he says. "They looked at acute toxicity and were convinced this was not going to be a less beneficial substitute than the others available."

'Depends On Where You Sit'

But Votaw said that for future rules, that may be difficult. "How you measure ... whether something is economically feasible depends on where you sit," he says. "If you are the seller of a product already using the alternative technology, obviously you demonstrate that there's something else that works and there is some market for it, at whatever price. But for the company that needs to make that transition, the cost of doing that could wipe them out. The question of who this is economically feasible [for] as well as technologically feasible for are questions that haven't been explored."

Votaw added that in the methylene chloride rule's cost-benefit analysis, "EPA also did a . . . balancing process that is really looking at the cost and benefits of the proposed rule and then one alternative and also the cost efficiency of whatever risk reductions with the proposed rule and one alternative."

In the case of methylene chloride rule, EPA "concluded it would cost less to do the proposed rule than a prohibition on sales to consumers. But even there, some analytical questions arise. It turns out that while the [rule] costs less, the benefits achieved were also much less."

Votaw stressed that when EPA did its cost benefit analyses and compared its options, the agency "did it without a lot of data. The requirement is to use data that is reasonably available, [so EPA] made judgements on what it had. The downside of that, of course, is maybe some bad decisions."

Votaw added that while the agency requests a lot of data on the existing chemicals it is evaluating, "when it comes to looking at the comparative studies, they looked at what they could find . . . [and that] may not have been adequate... The takeaway here, is that the data quality for looking at these alternatives is not likely to be of the same quality of data going into determining the underlying risk or exposures."-- Maria Hegstad (mhegstad@iwpnews.com)

EPA supports technology to improve sustainability & benefit farmers
AG Daily
https://www.agdaily.com/news/epa-technology-regulation-farmers/

In another effort to remove barriers to innovation, the U.S. Environmental Protection Agency has proposed a rule that will streamline the regulation of certain National Priority List sites that pose no risks of concern to humans or the environment. This action — which will be available for public comment for 60 days — delivers on a key directive under President Donald Trump's Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products.

"This new rule will provide critical new tools for America's farmers as they work to increase agricultural productivity, improve the nutritional value and quality of crops, fight pests and diseases, and boost food safety," said EPA Administrator Andrew Wheeler. "Embracing this technology through a transparent, consistent, and science-based process is long overdue, and will secure benefits to American agriculture well into the future."

"Agricultural biotechnology has been and will continue to be an essential tool in helping America's farmers and ranchers feed, fuel, and clothe the world," said U.S. Secretary of Agriculture Sonny Perdue. "From producers to consumers, all Americans deserve a government that delivers science-based, common-sense regulations that foster innovation, conserve resources, and protect public health — especially when it comes to the food supply. President Trump is committed to harmonizing our regulatory framework for agricultural biotechnology in order to equip our farmers with the tools they need to produce the world's safest, most abundant, and most affordable food supply."

Specifically, EPA is proposing exemptions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) for certain PIPs created through biotechnology. The agency has preliminarily determined that these substances meeting the exemption criteria have no risks of concern to humans or the environment.

EPA's proposed exemptions for PIPs created through biotechnology seek to facilitate the development of new tools for American farmers to protect their crops and control agricultural pests. By reducing antiquated regulations that restrict access to the market for biotechnology products, science-based innovations to agriculture will become far more accessible to American farmers. These improvements will have the potential to increase America's food supply.

PIPs are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the pesticidal substance. The existing regulatory exemption for PIPs is limited to those created through conventional breeding. The proposed exemption would allow for PIPs created through biotechnology to also be exempt from existing regulations if they:

- pose no greater risk than PIPs that meet EPA safety requirements, and
- could have been created through conventional breeding.

Under the proposed exemption, EPA would require developers of PIPs to submit either a self-determination letter or a request for EPA confirmation that their PIP meets the criteria for exemption; a developer could also submit both.

EPA's Pesticide Approval Risks Colony Collapse, Beekeepers Say
Maya Earls, Bloomberg Law
https://news.bloomberglaw.com/environment-and-energy/epas-pesticide-approval-risks-colony-collapse-beekeepers-say?usertype=External&bwid=00000174-4a3c-d7d2-a5ff-cebe58a00001&qid=6969933&cti=FGOV&uc=1320000080&et=CURATED_HIGHLIGHTS&emc=neve_hlt%3A4&context=email&email=00000174-4ad7-d58b-a7f4-eff747e90000&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzQtNGEzYy1kN2QyLWE1ZmYtY2ViZTU4YTAwMDAxIiwic2lnIjoicEtZYVd3SWxObk5sRTBBOUU1V1BiUDZSZzJZPSIsInRpbWUiOiIxNTk4OTkwNDU5IiwidXVpZCI6InhWdUtJZUR0bFBvaXRtK1JnNVYwMmc9PXc1a24vQm9saWxleHFqQnpoeTUwNFE9PSIsInYiOiIxIn0%3D

- Agency says benefits outweigh risks to bees
- Appeals court vacated EPA's initial approval

The EPA is ignoring a pesticide's risk to bees during a pollinator crisis that has "devastated" beekeepers and "poses a growing threat to American food security," an environmental group says in its brief filed in the Ninth Circuit.

Earthjustice filed its petition for review on behalf of the American Beekeeping Federation and the Pollinator Stewardship Council after the agency's 2019 decision to approve new uses for sulfoxaflor. The chemical is an insecticide produced by Corteva Agriscience, formerly a part of DowDuPont Inc.

The U.S. Court of Appeals for the Ninth Circuit previously ordered the Environmental Protection Agency to remove sulfoxaflor from the market. The EPA responded by barring the use of the chemical on certain plants during the 2016 growing season. Those restrictions were reversed in July 2019 when the agency authorized sulfoxaflor's use on all crops, including citrus and strawberries that attract bees.

The EPA said the pest-control benefits outweighed the chemical's risk to bees. But it lacked the data to properly assess those risks and instead focused exclusively on information provided by Dow, Earthjustice said in its opening brief filed Monday.

The agency also authorized sulfoxaflor's use on bee-attractive crops without notifying the public that Dow had re-applied to register those uses, according to the filing. Had they been notified, beekeepers say they would have provided evidence showing the economic cost of increasing risks to bees.

The EPA's actions violated the Federal Insecticide, Fungicide, and Rodenticide Act, and the agency's decision will have significant economic consequences for commercial beekeepers, farmers, and consumers, the brief said.

The group is seeking an order vacating the agency's decision.

Earthjustice represents the ABF, the PSC, and individual commercial beekeeper Jeffrey Anderson.

The Department of Justice represents the federal government.

The case is Pollinator Stewardship Council v. Wheeler, 9th Cir., No. 19-72280, 8/31/20.

EPA Chemical Risk Evaluations – Stakeholders Diverge on Whether and How EPA Must Include Dietary Exposures
Cynthia Stroman, JD Supra Blog
https://www.jdsupra.com/legalnews/epa-chemical-risk-evaluations-18630/

In the 2016 amendments to the Toxic Substances Control Act (TSCA), Congress directed EPA to evaluate the risk of all chemicals in U.S. commerce.1 The amendments also set specific deadlines for the initial sets of evaluations, and EPA has issued draft scopes for several risk evaluations that discuss food products. The 2016 amendments did not change the original exclusion for chemical substances that are foods or food additives under the Federal Food, Drug, and Cosmetic Act.2 Due to this exclusion, these chemical risk evaluations may not on the surface seem relevant to the food and beverage industry. However, the amendments also required EPA to assess "information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations."3 This directive, combined with statutory text concerning integrating or aggregating exposures, features prominently in the comments several stakeholder groups submitted to EPA on draft scopes for risk evaluations in progress.

FOODS AND FOOD ADDITIVES GENERALLY EXCLUDED FROM "CONDITIONS OF USE" – MANUFACTURING AND PROCESSING INCLUDED FOR SOME SUBSTANCES
In draft scopes that mention foods and food additives, EPA consistently states that such uses are "outside the scope of TSCA." The draft scope for formaldehyde excludes use of formaldehyde in food packaging adhesives and sugar refineries.4 The draft scope for di-cyclohexyl phthalate excludes articles for packaging, transporting or holding food; cellophane; and paper and paperboard components intended to come into contact with dry food or aqueous and fatty foods.5 The draft scope for butyl benzyl phthalate also excludes food packaging materials.6 However, although EPA does not intend to evaluate food and food additive uses as conditions of use, EPA intends to include production and processing of food packaging and related food and beverage materials in several of the evaluations.7 Not surprisingly, EPA's hybrid approach prompted discussion in a range of comments.

STAKEHOLDERS ASSERT VARYING POSITIONS ON WHETHER EPA MUST EVALUATE FOOD EXPOSURES
Several nongovernmental organizations argued in their comments that, even if not conditions of use required to be evaluated, exposures to chemical substances in food must nonetheless be included in the evaluation.

Any potential health effects from exposure to such a chemical would be a function of a person's total exposure to the chemical, regardless of source. Credibly assessing the risk of that chemical requires considering all sources of exposure to it, even if some of them are deemed "background sources" that either cannot be specifically identified or fall outside of TSCA's regulatory jurisdiction.8

Other commenters echoed this view of EPA's assessment of food exposures as "highly variable and problematic."9

While EPA is only mandated to conduct a risk assessment for TSCA conditions of use, EPA must still account for non-TSCA uses as background exposures when evaluating whether conditions of use EPA does consider present unreasonable risk. This is because it is impossible to determine if the conditions of use that TSCA does regulate present an unreasonable risk if non-TSCA uses that contribute to a baseline level of phthalates in the human body are ignored.10

Yet other commenters focused on the requirement to assess "potentially exposed or susceptible sub-populations," arguing that exclusion of dietary exposures will overlook most exposures to children.11

In contrast, manufacturer commenters focused on dietary exposures in a limited manner. At most, they requested exclusion of certain uses from the evaluations.12 It is unclear whether such requests concerned only conditions of use or also included the background exposures in which the other stakeholders would place dietary exposures.

UP NEXT – RISK EVALUATIONS

After EPA finalizes the scope documents, the substances under review will enter the risk evaluation stage. Although stakeholders weighing in on the draft scopes do not appear to have included food and beverage companies or the prominent trade associations for such companies, the risk evaluation stage provides an opportunity to engage with EPA and directly weigh in on the central question of how EPA should address both the conditions of use directly regulated under TSCA and the dietary exposures asserted to have relevance in the TSCA risk assessment process.

Peer Review Finds EPA's Asbestos Risk Evaluation Flawed
Tim Potvak, Asbestos.com
https://www.asbestos.com/news/2020/09/02/epa-asbestos-risk-evaluation-peer-review/

The Science Advisory Committee on Chemicals found considerable failings and an underestimation of danger to the general public in a draft risk evaluation of asbestos submitted earlier this year by the U.S. Environmental Protection Agency.

SACC, which serves as a scientific, peer-review mechanism for the EPA, released its recommendations last week in the ongoing governmental reevaluation of asbestos.

This is the latest step in the amended Toxic Substances Control Act that requires the EPA to conduct evaluations on specific chemicals to determine whether they present unreasonable risk under conditions of use.

The committee was comprised of 14 scientists, medical doctors and Ph.D.s from around the country, along with another 10 ad hoc peer reviewers with asbestos experience.

SACC's ad hoc panel had several members who routinely testify on behalf of plaintiffs in asbestos litigation, but no experts who testify on behalf of defendants. They met for four days in June to dissect the EPA's original draft risk evaluation of the dangers of asbestos exposure.

"Overall, EPA's environmental and human health risk evaluations for asbestos was not considered adequate and results in low confidence in the conclusions," according to the executive summary.

"This [draft risk evaluation] does not fit the reality of total exposure to asbestos," the summary concluded. "The estimate for total exposure to asbestos is deficient. This DRE includes only a limited slice of the exposure."

Final Asbestos Evaluation Could Lead to Changes
When the final evaluation is complete, the EPA will have several options. It could propose further limits on asbestos use and distribution, leave the current regulations in place, or potentially recommend a complete ban on the toxic mineral.

"We're pleased to see the SACC report confirmed what many of us knew as soon as the draft risk evaluation was released [in March]," Brent Kynoch, managing director of the Environmental Information Association in Chevy Chase, Maryland, told The Mesothelioma Center at Asbestos.com. "The EPA's draft evaluation contained multiple omissions and exclusions. We can no longer rely on the EPA."

Kynoch is not part of the committee, but he participated in the public comment segment of the meeting. He is one of many who believe the U.S. Congress should legislate a comprehensive ban on asbestos.

An endorsement by the EPA in its final evaluation could play a role in any legislative changes.

Original EPA Evaluation Not Broad Enough
The EPA's original draft risk evaluation, which examined 33 conditions of use, cited "unreasonable risk to workers, occupational non-users, consumers and bystanders" in the limited number of asbestos products still being imported and used today.

It found unreasonable risk of occupational asbestos exposure throughout the chloralkali and oil industries. It also found problems with asbestos products such as sheet gaskets, brake blocks and other vehicle friction items.

The committee agreed with many of the EPA's findings, but said the evaluation was much too limited in scope overall. It cited several problems with the draft analysis. Among the most glaring were:

It did not account for the risks of legacy asbestos from products no longer produced but which are found in hundreds of thousands of older buildings across the country.
The analysis evaluated only the chrysotile type of asbestos — the most common — but not amphibole, crocidolite and serpentine asbestos fibers. It also did not look at other asbestos-like minerals.
It evaluated risks for and deaths only from mesothelioma, a rare and aggressive cancer. It failed to explore other asbestos-related diseases such as lung cancer, ovarian cancer and asbestosis.
There was no assessment of asbestos contamination in talc and other widely used consumer products.
Linda Reinstein, president of the Asbestos Disease Awareness Organization, was part of the public comment segment of the meeting. The organization also released a statement in response to the SACC report.

"The draft risk evaluation is a no-go," said Reinstein. "[It] is fundamentally flawed and understates the serious risks of asbestos to public health. The U.S. needs an asbestos ban without any loopholes or exceptions."

EPA Promising Changes to Risk Evaluation
In releasing the SACC report, the EPA said it was in the process of reviewing the recommendations and would use some of the issues to improve its final risk evaluation.

The agency said it specifically would consider legacy uses and associated disposal of asbestos in a supplemental scope document that would be released later this year.

++

For more news, visit:

- Inside EPA: https://insideepa.com/
- Inside TSCA: https://insideepa.com/inside-tsca-home
- Bloomberg Environment and Energy: https://news.bloombergenvironment.com/environment-and-energy/

If you'd like to be removed or would like to add someone to the listserv please contact Bailey Rosen at Rosen.Bailey@epa.gov. Feedback and interesting articles are welcomed. Thanks and enjoy!

And while you're reading…. Remember to shoot your coworkers a shooting star!